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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,142	03/15/2002	Yutaka Yamagata	2002-0345 A	1458

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EXAMINER	
BENNETT, RACHEL M	

ART UNIT	PAPER NUMBER
1615	7

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/088,142	Applicant(s) YAMAGATA ET AL.	
	Examiner Rachel M. Bennett	Art Unit 1615	

-- Th MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,4,6*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The examiner acknowledges receipt of IDS filed 3/15/02 and Preliminary Amendment A and IDS filed 4/5/02, and Supplemental IDS filed 5/4/03.

Specification

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-13, 16-17, 19-22 of U.S. Patent No. 6,482,864. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a method of producing a protein powder, which comprises contacting a protein containing solution with a refrigerant carrier, freezing the solution and then drying.

3. Claim 17 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,191,107. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a sustained-release preparation which comprises lactic acid/glycolic acid copolymer having the molar ratio of the lactic acid/glycolic acid of 60/40 and a growth hormone.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Takeda (WO 97/01331).

Applicants claim a sustained release preparation which comprises lactic acid/glycolic acid copolymer having the molar ratio of the lactic acid/glycolic acid of 60/40 to 70/30 and a growth hormone.

Takeda claims a sustained release preparation produced by dispersing a bioactive polypeptide in an organic solvent containing a biodegradable polymer metal salt, and subjecting the resulting dispersion to formation. See claims 19, 22, 1, 6, and 8. The bioactive polypeptide is a hormone, specifically a growth hormone. See claim 8. The biodegradable polymer is a lactic acid-glycolic acid copolymer, wherein the copolymer is about 100/0 to about 40/60. See claim 14. Therefore, this claim is anticipated.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeda (WO 97/01331).

Applicants claim a process for producing a protein powder which comprises contacting a protein containing solution with a refrigerant carrier, freezing the solution at a cooling rate of about –300 to –10 deg C/min. and then drying.

Takeda discloses a method of producing a sustained release preparation which comprises dispersing a bioactive polypeptide in an organic solvent containing a biodegradable polymer metal salt and subjecting the resulting dispersion to formation. See page 2. The polypeptide is a hormone, specifically a growth hormone. The biodegradable polymer is an aliphatic polyester, specifically a lactic acid-glycolic acid copolymer. See page 3. The lactic-acid glycolic acid copolymer is in the range of about 60/40 to about 25/75. See page 5. Reference Example 1 discloses the process of lyophilizing lactic acid-glycolic acid copolymer. Reference Example 4 discloses a process for producing a protein powder comprising dissolving a protein (insulin) in hydrogen chloride solution. Then the solution was dialyzed against hydrogen chloride solution 3 times. The dialysate was further dialyzed against aqueous ammonium acetate solution once, distilled water once and then lyophilized. Example 1 discloses adding the lactic acid glycolic

acid copolymer powder (Reference Example 1) dissolved in an organic solvent to the lyophilized protein powder (Reference Example 4). The mixture was agitated and the microcapsules were recovered by centrifugation. The pellet was rinsed with distilled water and lyophilized to provide a powdery insulin containing microcapsule. Takeda is silent with regards to the cooling rate. Applicants claim the cooling rate to be about –300 to –10 deg C/min.

While the reference is silent regarding the cooling rate, differences in cooling rate will not support patentability of subject matter encompassed by the prior art unless there is evidence indicating such cooling rate is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Therefore, absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have optimized the cooling rate depending on the protein used. The expected result would be a process for producing a protein powder, which comprises contacting a protein-containing solution with a refrigerant carrier, freezing the solution at optimal cooling rate and then drying.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett
June 9, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600